Opportunities for Prevention of Perinatal Group B Streptococcal Disease: A Multistate Surveillance Analysis

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Objective: **To evaluate the potential impact of ACOG and Centers for Disease Control and Prevention (CDC) consensus strategies for the prevention of perinatal group B streptococcal disease.**

Methods: **We evaluated cases of early-onset group B streptococcal disease identified by active surveillance during 1995, in four areas in North America with an aggregate 186,000 births per year. We reviewed the hospital records of mothers and infants and any prenatal records available on site. Cases were determined to be preventable based on whether group B streptococcal screening could have been performed prenatally, sensitivity of screening, presence of obstetric complications, and opportunity to administer antibiotics.**

Results: **We reviewed records for 245 of 246 infants with early-onset group B streptococcal disease in the surveillance areas. Most of the 53 case-mothers who delivered preterm and 192 who delivered full-term had had at least one prenatal visit (83% and 99%, respectively). Few case-mothers had prenatal group B streptococcal screening cultures, although compliance was high for other prenatal screening tests. Fifty-four percent of case-mothers had a recognized obstetric risk factor for group B streptococcal disease: labor or rupture of membranes at less than 37 weeks, rupture of membranes for 18 hours or longer, or temperature 38C or greater. The estimated preventable portion of early-onset group B streptococcal cases was 78% for the screening-based approach (range 74% to 82% by area), compared with 41% for the risk-based approach (range 39% to 53% by area).**

Conclusion: **Comprehensive implementation of either of the recommended prevention strategies could potentially prevent a substantial proportion of early-onset group B streptococcal disease. (Obstet Gynecol 1997;90:901–6.)**

In response to the continued burden of perinatal disease due to group B streptococcus and the inconsistent implementation of prevention practices,[1,2] the Centers for Disease Control and Prevention (CDC) and ACOG published consensus guidelines during 1996, promoting use of one of two strategies for administering intrapartum antibiotic prophylaxis. Two strategies were detailed, one based on late prenatal screening cultures, and the other on obstetric risk factors evident at delivery (Table 1).[3,4] Estimates of the potential impact of these approaches have been limited to data that were collected at individual hospitals[5–7] or larger studies that may not have been representative.[8,9] Large-scale clinical experience with either of these approaches is not yet available. To measure the potential impact of the new guidelines, we investigated cases that occurred during 1995 of early-onset group B streptococcal disease identified by active, population-based surveillance and collected prenatal and intrapartum information on mothers of infected infants.

Materials and Methods

Case finding was conducted in an aggregate population of 12.5 million, consisting of residents of eight counties in the Atlanta metropolitan area (health district III), five counties in Tennessee, the entire state of Maryland, and the metropolitan Toronto/Peel region in Ontario, Canada. An estimated 186,000 births occurred in the surveillance population during 1995 (data from National Center for Health Statistics and Office of the Registrar General). Cases were identified through an active labo-

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Table 1. Risk Factors That are Indications for Intrapartum Antibiotic Prophylaxis Based on Consensus Strategies

Condition	Screening-based strategy[3,4]	Risk-based strategy[3,4]
Group B streptococcal bacteriuria	X	X
Previous delivery of infant with group B streptococcal disease	X	X
Positive group B streptococcal culture at 35–37 wk	X	—
Rupture of membranes ≥ 18 h	*	X
Gestation < 37 wk	*	X
Temperature ≥ 38C	†	X

* Only if group B streptococcal culture not done or results not available.

† Temperature 38C or greater in women with negative prenatal group B streptococcal cultures may be an indication for therapeutic intrapartum antibiotics for suspected maternal infection and may require broader-spectrum treatment than the agents recommended for group B streptococcal prophylaxis.

ratory-based surveillance system, which was described previously.[10,11]

A case of early-onset disease was defined as isolation of group B streptococci from a normally sterile site (eg, blood, cerebrospinal fluid) in an infant younger than 7 days of age during 1995 for the metropolitan Toronto/Peel region and from November 1, 1994, through October 31, 1995, for all other areas.

To evaluate the applicability of the screening-based approach in both preterm and term deliveries, we made certain assumptions. The screening-based strategy includes collection of cultures for group B streptococci at 35–37 weeks. If a woman presents with labor or rupture of membranes before 37 weeks and a culture result for group B streptococci is not available, she is given intrapartum antibiotic prophylaxis. For term deliveries, not only must a woman be screened, but the test results must be available to the practitioners at delivery. Women with group B streptococcal colonization identified by prenatal culture are offered intrapartum antibiotic prophylaxis (Table 1). If no information on prenatal culture status is available because the case-mother did not have prenatal care or because her records were not available at delivery, we determined whether she had an obstetric risk factor (rupture of membranes for 18 hours or longer, or intrapartum temperature 38C or greater). In the screening-based strategy, obstetric risk factors lead to administration of intrapartum antibiotics when culture information is unknown. We assumed that women with prenatal care could have had screening cultures collected and that appropriately processed cultures collected at 35–37 weeks would detect 87% of intrapartum group B streptococcal carriers.[12] We also assumed that a minimum of 1 hour in the hospital was needed to provide intrapartum antibiotic prophylaxis. We assumed that antibiotics would prevent disease in 95% of recipients.

The risk-based approach recommends antibiotic prophylaxis to women with any of the obstetric risk factors for early-onset group B streptococcal disease: labor or rupture of membranes at less than 37 weeks' gestation, rupture of membranes for 18 hours or longer, or temperature 38C or greater (Table 1). To evaluate the applicability of the risk-based approach, we made the same assumptions for the screening-based approach. We also assumed that a risk factor needed to be evident at least one hour before delivery for it to be acted upon.

To evaluate whether cases might have been preventable by either the screening-based or the risk-based approach, we collected data from the hospital medical records of both mothers and infants including any prenatal records available in the hospital medical record. If the infant was transferred during the hospital stay, we reviewed the charts at both hospitals. If prenatal records were not available, birth certificate data were substituted.

Information was obtained about case-mothers diagnosed with group B streptococcal bacteriuria and case-mothers who had previously delivered infants with group B streptococcal disease, who would meet the criteria for treatment with intrapartum antibiotics under either strategy. Deliveries were defined as premature if gestational age was less than 37 completed weeks. Prolonged rupture of membranes was defined as rupture of membranes beginning 18 hours or longer before delivery.

We compared differences in proportions of dichotomous variables using the χ^2 or Fisher exact test when appropriate. Rates of early-onset disease were calculated using the number of live births during 1995 in each area for the denominators.

Results

We identified 246 infants younger than 7 days of age who resided in any of the surveillance areas and from whom group B streptococcus was isolated from a normally sterile site during the study period. The rate of early-onset group B streptococcal disease varied between sites from 0.8 (in Maryland) to 1.9 (in Georgia) per 1000 births.[11] In 234 (95%) of the cases, we were able to review all neonatal and maternal charts. For a single case, none of the charts could be located. In 12 cases, we could not locate either the maternal chart ($n = 6$) or the chart from the hospital to which the newborn was transferred ($n = 6$). For this analysis, we included all 245 cases for which we had at least partial data.

A higher proportion of case-mothers were black, unmarried, and younger than 20 years of age, compared with all U.S. births during 1995 (Table 2).[13] No case-mothers had previous infants with group B streptococcal disease, and only four had group B streptococcal bacteriuria. Although prematurity was more common among case-infants than in the general population, almost 80% of disease occurred among full-term infants. Whereas 45 (19%) case-mothers received antibiotics, the median (range) interval between antibiotic administration and delivery for these women was 1.4 (0.1–101) hours. The median (range) amount of time for which case-mothers were in the hospital was 13 hours (0 hours–25 days) before delivery.

Although the most common clinical syndrome was sepsis, 21% of case-infants presented with asymptomatic bacteremia. In 86% of symptomatic cases, onset of illness occurred within 12 hours of birth. Five percent of symptomatic case-patients had onset after 24 hours of age. Fifty-nine (24%) case-infants required either mechanical ventilation (20%) or transfer to another institution (11%). Death occurred in five (3%) full-term and eight (15%) premature case-infants (P = .003). The infants' median (range) length of stay was 10 (1–77) days.

Table 3 shows information regarding prenatal care for case-mothers. Ninety-six percent of case-mothers had at least one prenatal visit. Using the Kessner Adequacy of Prenatal Care Index,[14] 92% of case-mothers had care rated as at least intermediate, compared with 79% of case-mothers with care rated as at least intermediate using the Adequacy of Prenatal Care Utilization Index.[15] Only 12% of case-mothers had group B streptococcal cultures collected from the vagina and rectum (Table 3).

Of 192 full-term deliveries, one case-mother had no prenatal care, five had no prenatal records available at the hospital at delivery, and three arrived at the hospital less than 1 hour before delivery. For nine additional case-mothers, information was incomplete for these variables. Therefore, 174 (90%) case-mothers had prenatal care, available prenatal records, and adequate time for intervention. In 43 (81%) of the 53 preterm deliveries, the case-mother arrived at least 1 hour before delivery. Therefore, in 217 (88%) cases, there was an opportunity for intervention if the screening-based approach had been followed.

The case-mother who delivered full-term without prenatal care had prolonged rupture of membranes, but she presented to the hospital less than 1 hour before delivery. Three of the five case-mothers who had no prenatal records available at delivery had prolonged

Table 2. Characteristics of Mothers of Infants with Early-Onset Group B Streptococcal Disease

Characteristic	Case-mothers (n = 245)* (%)	% of 1995 US births (n = 4 million)[13]
Black race	104 (42)	15†
Age < 20 y	44 (18)	13†
Unmarried	98 (40)	32†
Completed ≥ 12 y of school	121 (76)	77
Primiparity	102 (42)	41
Previous infant with group B streptococci	0 (0)	ND‡
Group B streptococcal bacteriuria this pregnancy	4 (2)	ND‡
Premature delivery	53 (22)	11†
Cesarean delivery	75 (31)	21†
Received antibiotics	45 (19)	ND‡
Received antibiotics ≥ 4 h before delivery	9 (4)	ND‡

* Denominators varied for some because of missing information.
† P < .05.
‡ No data available.

Table 3. Characteristics of Prenatal Care Among Case-Mothers

Characteristic	Case-mothers (n = 245) (%)*
Full-term deliveries (n = 192)	
Any prenatal care	189† (99)
Any third-trimester prenatal visit	174‡ (99)
Preterm deliveries (n = 53)	
Any prenatal care	44 (83)
Any third-trimester prenatal visit	22§ (79)
Kessner Index[13]	
Adequate	220 (90)
Intermediate	4 (2)
Inadequate	13 (5)
Missing	8 (3)
Adequacy of Prenatal Care Utilization Index[14]	
Adequate plus	59 (24)
Adequate	82 (33)
Intermediate	55 (22)
Inadequate	36 (15)
Missing	13 (5)
Prenatal testing (among those with prenatal care, n = 231)	
Group B streptococcal genital cultures	
Vaginal or rectal culture	28 (12)
Third-trimester culture	24 (10)
Culture ≥ 35 wk	4 (1)
Syphilis serology	220 (95)
Hepatitis B serology	219 (95)
Gonorrhea culture	128 (55)
Chlamydia culture	125 (54)

* Denominators varied for some because of missing information.
† Data missing for 2 (1%).
‡ Data missing for 17 (9%).
§ Data missing for 25 (47%).

Table 4. Estimated Number (%) of Preventable Cases of Early-Onset Group B Streptococcal Disease by Screening-Based or Risk-Based Approach, for a Multistate Surveillance Population, 1995

Characteristic	Screening-based approach (%)	Risk-based approach (%)
Preterm deliveries (n = 53)		
Admission ≥1 h before delivery	43	43
Receipt of antibiotics*	43	43
Preventable cases (% of preterm)†	41 (77)	41 (77)
Full-term deliveries (n = 192)		
Any prenatal care	189	NA‡
Group B streptococcal screening§	189	NA‡
Positive group B streptococcal screening culture‖	164	NA‡
Prolonged rupture of membranes or fever for ≥1 h before delivery	2¶	64
Admission ≥1 h before delivery	159	61
Receipt of antibiotics*	159	61
Preventable cases (% of full-term)†	151 (79)	58 (30)
All deliveries (n = 245)		
Preventable cases (baseline assumptions)	192 (78)	99 (41)
Sensitivity analysis		
Preventable cases—85% with prenatal care	170 (70)	99 (41)
Preventable cases—70% with prenatal care	165 (67)	99 (41)
Preventable cases—98% antibiotic efficacy	198 (81)	102 (42)
Preventable cases—75% antibiotic efficacy	151 (62)	78 (32)
Preventable cases—admission ≥4 h before delivery to ensure opportunity for intervention	175 (71)	89 (36)

* Assuming all women who presented 1 h or more before delivery would receive appropriate antibiotics.

† Assuming efficacy for intrapartum antibiotics of 95%.

‡ Not applicable.

§ Assuming in an aggressive prevention program all case-mothers with prenatal care would have group B streptococcal screening and records available at hospital at delivery.

‖ Assuming screening culture sensitivity at 87%.[12]

¶ Number of case-mothers without known prenatal care (n = 3) estimated to have risk factors (54%).

rupture of membranes and presented 1 hour or more before delivery. Following the screening-based protocol, these women would also have been offered intrapartum antibiotics.

At least one of the obstetric risk factors that are indications for prophylactic antibiotics in the risk-based approach was evident in 129 (54%) case-mothers, and 117 case-mothers had evidence of this risk factor at least 1 hour before delivery. Of these, 104 case-mothers were in the hospital at least 1 hour before delivery and would have been offered intrapartum antibiotics using a risk-based approach.

Thirty percent (39) of case-mothers with risk factors did receive at least one dose of appropriate antibiotics before delivery. The median interval between antibiotic receipt and delivery was 1.4 hours. Only seven of these case-mothers with risk factors received antibiotics at least 4 hours before delivery, and three of these had intrapartum fever by the time antibiotics were initiated.

Applying a sensitivity of group B streptococcal screening cultures of 87%[12] and an antibiotic efficacy of 95%, the proportion of cases of early-onset group B streptococcal disease that were preventable was 78% for the screening-based approach (range 74% to 82% by geographic area) and 41% for the risk-based approach (range 39% to 53% by geographic area) (Table 4, Figure 1).

Discussion

Our study demonstrates that use of either of the two prevention strategies recommended in 1996 by the CDC and ACOG could have potentially prevented a substantial proportion of early-onset group B streptococcal cases identified in a large, geographically diverse population during 1995. A screening-based strategy relies on detecting group B streptococcal colonization by prenatal screening and using these results to guide intrapartum antibiotic chemoprophylaxis. One concern about this approach is that it would be ineffective for women who have not received prenatal care or whose prenatal records are not available to health care providers at delivery. Furthermore, rates of group B streptococcal disease have been high in hospitals serving indigent populations, and both black women and teenage mothers are at increased risk of delivering infected infants.[8,9] These earlier observations suggested that women at high risk for group B streptococcal disease

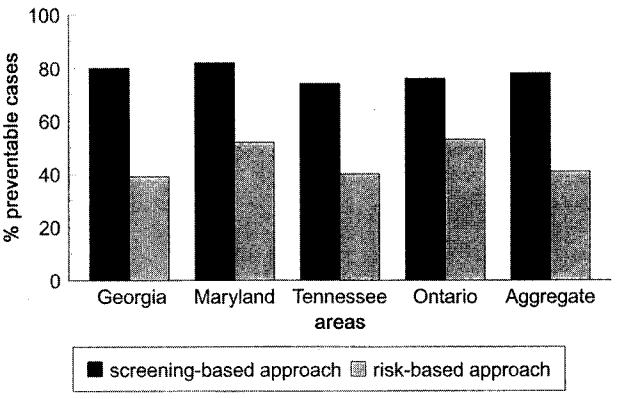

Figure 1. Proportion of early-onset group B streptococcal disease cases preventable by screening-based or risk-based strategy, by area.

may also have poor access to prenatal care and might therefore be missed by a screening-based approach.

Most case-mothers had at least one prenatal visit during the third trimester, which could have provided the opportunity for group B streptococcal screening cultures to be collected. Access to prenatal care among the mothers of infants with group B streptococcal disease in our study actually was similar to that in the general population. Only 4% of case-mothers had no prenatal visits, compared with 4% of U.S. births in 1995 who had late or no prenatal care.[13] Among case-mothers, the proportion whose care was rated inadequate (5% by Kessner Index, and 15% by Adequacy of Prenatal Care Utilization Index) was similar to the proportion of U.S. births in 1980 rated as having inadequate care by these indices (7.7% and 16.7%, respectively).[15]

Our analysis suggests that the screening-based approach has the potential to prevent more cases of early-onset group B streptococcal disease than the risk-based approach, because nearly half of case-mothers had no risk factors. However, we did not directly measure the effectiveness in clinical practice of either strategy, which could be substantially lower than predicted. The screening-based approach may be complicated to implement because appropriate procedures must be followed at multiple points. The approach requires prenatal screening with appropriate culture methods. Culture of both vagina and rectum has the highest yield, whereas cervical cultures have very low yield.[16,17] The new guidelines recommend that patients be screened for group B streptococci at 35–37 weeks' gestation, when concordance with intrapartum culture status is high,[12,18] and that cultures be processed with selective broth media.[3,4] In 1994, only 6% of microbiology laboratories in a multistate survey were using selective broth media[2]; therefore, the effectiveness of the screening-based strategy in clinical practice requires enhancing laboratory compliance. Finally, the screening-based approach requires transfer of laboratory results to the hospital, where health care providers must act on them.

Prenatal records were unavailable to health care workers at delivery for only five case-mothers who delivered at full term and had received prenatal care. We were not able to assess whether the results of group B streptococcal screening cultures were available at delivery, because very few case-mothers were screened, which may not be surprising because U.S. consensus guidelines were not released until mid-1996. Ensuring the availability of these results is essential for this strategy to succeed and will likely necessitate development of appropriate laboratory reporting mechanisms.

The screening-based strategy recommended by the CDC[3] and ACOG[4] includes contingency plans for women who have either no prenatal care or no prenatal screening result available at delivery, as would be the case with most preterm deliveries when there is no opportunity to collect a 35–37 week culture. Of the 59 case-mothers who fit this description, 53 would have been offered intrapartum antibiotic prophylaxis because of preterm delivery, and three others would have received intrapartum antibiotics because of obstetric risk factors. Only three case-mothers with no prenatal care had no obstetric risk factors, and one of these three presented too late (10 minutes before delivery) for intervention by an intrapartum strategy.

According to the risk-based strategy, 54% of case-mothers had an obstetric risk factor and should have received intrapartum antibiotic prophylaxis. One-hundred ten case-mothers for whom we had complete information had no identifiable risk factors and would not have been targeted for prevention using this approach. The proportion of case-mothers considered to have risk factors is lower than in most previous studies.[5,8,9] An earlier algorithm for intrapartum antibiotic chemoprophylaxis advocated using a shorter duration of rupture of membranes (12 hours) or a lower temperature (37.5C) as criteria for prophylaxis. These less stringent clinical characteristics were proposed to be applied to group B streptococcal carriers, not to all pregnant women.[5] Use of these criteria among the case-mothers in this study would increase the proportion identified as having risk factors to 72% but would probably increase antibiotic use substantially.

Only 19% of case-mothers received any intrapartum antibiotic chemoprophylaxis, and illness in their infants might be considered the result of antibiotic failure. Women received antibiotics a median of 1.4 hours before delivery, and only nine cases occurred when maternal intrapartum antibiotic chemoprophylaxis had begun at least 4 hours before delivery. These breakthrough cases may be more likely to occur when the mother already has advanced infection; in fact, four of these nine case-mothers had a temperature greater than or equal to 38C by the time antibiotics were begun.

Because our study looked at group B streptococcal cases and did not measure antibiotic use among all women delivering in the surveillance areas, we do not have data with which to estimate the number of cases that already were being prevented. Health care practitioners might already have been using antibiotic prophylaxis for some women, and early-onset group B streptococcal disease had declined by 1995 in one of the four areas in this study.[11] If prevention had been systematically directed at women with risk factors, we would expect areas with lower rates of disease to have a high proportion of the remaining cases occurring among women without risk factors. However, the percent of cases without risk factors did not differ signifi-

cantly between areas (Figure 1). Even in the area with the highest rate of early-onset disease, our data suggest that the risk-based approach is unlikely to prevent more than 41% of cases.

Implementation of either of these strategies should prevent a large number of neonatal group B streptococcal infections, but cases will still occur. Development of sensitive rapid screening tests for group B streptococci that can detect women who carry group B streptococci at the onset of labor or membrane rupture would potentially enhance prevention effectiveness. Availability of vaccines against group B streptococci that permit transplacental transfer of protective antibodies to the fetus could potentially address prevention of late-onset disease as well as early-onset cases. In the meantime, the two strategies recommended by the CDC and ACOG are an interim solution. As with all medical interventions, the acceptability of these approaches to expectant mothers, the preferences of their caregivers, and the costs associated with these programs certainly will have an impact on how they are used in practice. Either of these strategies may increase antibiotic use in the intrapartum period, which could increase adverse reactions, lead to development of antimicrobial resistance in peripartum pathogens, and complicate the management of newborns. Despite these theoretic concerns, adoption of one of the strategies has been recommended for all institutions, because the clinical and economic benefits of prevention outweigh the potential risk of the strategies.[19] Although continued surveillance is necessary to evaluate the effectiveness of these protocols, this study of a large, geographically diverse population suggests they offer the potential to substantially reduce the leading cause of sepsis and meningitis among newborns in the United States.

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